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ARMSTRONG LABORATORY

Test and Evaluation of the Protocol Systems Propaq 106EL Physiologic Patient Monitor

Kindra A. Edman, First Lieutenant, USAF, BSC

October 1996

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NOTICES

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13. ABSTRACT *(Maximum 200 words)*

The Propaq 106EL is a portable patient monitor capable of monitoring, non-invasive blood pressure, invasive blood pressu.re, patient temperature, pulse oximetery, and respiratory rate. A Protocol Universal Power Adapter, Part Number 503-0054-00 100 - 120VAC 50/60 Hz line voltage to low voltage DC 16 - 24 VDC. This operates the 106EL and charges the internal battery . The Propaq 106EL can receive 28 VDC input power via the Protocol DC power cord. The internal battery lasts approximately 4 - 8 hours with a recharge time between 6 - 12 hours.

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ACKNOWLEDGMENTS

I would like to thank all those who helped and advised during the evaluation of the Protocol Systems Propaq 106EL. I would especially like to thank Lt Col Jacqueline D. Hale, MSgt Victor Elizondo, TSgt Butch Blake, TSgt Allen Jones, TSgt Mary Thomas, Mr. Edward Hade, Mr. Douglas Townsend, personnel from ASC/ENAI Wright Patterson AFB, AL Laboratory of Aerospace Cardiovascular Research, personnel from the 332nd at Randolph AFB, and Ms. Grace Day, Director of Marketing for Protocol Systems.

TESTING AND EVALUATION OF THE PROTOCOL SYSTEMS PROPAQ 106EL PHYSIOLOGIC PATIENT MONITOR

BACKGROUND

Air Training Command Surgeon General and the Department of Surgery, Wilford Hall USAF Medical Center briefed HQ AMC/SG (Brig Gen Roadman) on the feasibility of a Critical Care Aeromedical Transport Team (CCATT). During this meeting a request for evaluation of a patient monitor for air worthiness was presented. The Director, Aeromedical Evacuation and Medical Plans & Requirements requested the Human Systems Center at Brooks AFB have Armstrong Laboratory evaluate the Propaq 106EL compatibility with aeromedical aircraft systems and the airborne environment.

DESCRIPTION

The Propaq 106EL, SN: AE00127 with modules: BD00128, MD00153, and CI00128 (component printer, pulse oximeter, and carbon dioxide monitor unit), will hereby be referred to as the 106EL (figure 1). This unit is a light weight portable patient monitor capable of monitoring the following: ECG (1 channel: 3-lead); NIBP, noninvasive blood pressure, (1 channel: cuff); IBP, invasive blood pressure, (2 channels); temperature (1 channel: YSI); pulse oximetry (1 channel: SpO_2); CO_2 (1 channel); and respiratory rate (figure 2). This unit has a printer and HP Connector-Compatible Side Panel. The display in the 106EL is electroluminescent (EL). With printer/SpO_2/CO_2, the dimensions of the unit are: height, 9.8 in (24.9 cm); Width, 8.3 in (21.1 cm); depth, 7.3 in (18.5 cm); weight, 12.3 lbs (5.6 Kg). DC input power required: 12 - 28 Volts, 25 Watts. The 106EL is powered from an internal, 8 V/6 Amp Hr, sealed lead acid battery or suitable external power source. Battery life is rated at 4-8 hours depending on product configuration with a recharge time at 6 to 12 hours.

The Protocol Universal Power Adapter, Part Number 503-0054-00 converts 100-120VAC, 500 mA, 50/60 Hz line voltage to low voltage DC, 16 - 24 VDC, 25 watts. It operates the 106EL and charges the internal battery. The 106EL can also receive the required input power from Protocol DC power cord, Part Number 008-0290-00. In order to use DC power on USAF aircraft, a Hubbell Twist - Lock® plug, Catalog Number 7545C or equivalent is required to be installed. For a detailed description of 106EL options reference the Propaq User's Guide.

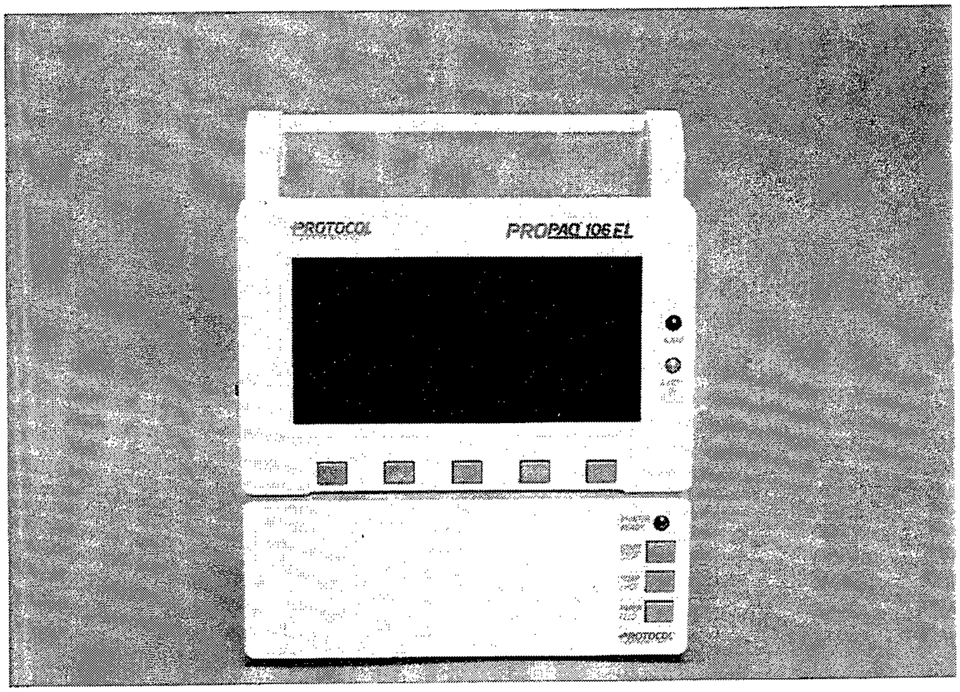


Fig. 1 Protocol Systems Propaq 106EL Monitor and Expansion Module.

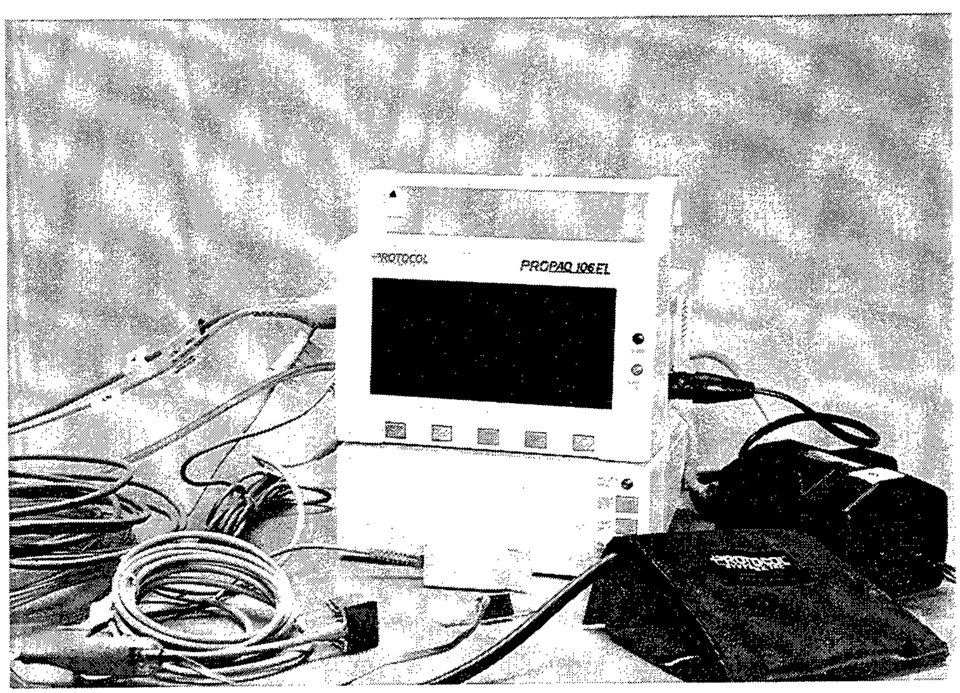


Fig. 2 Protocol Systems Propaq 106EL and its connections.

METHODS

Aeromedical Research personnel derived test methods, procedures and performance criteria from various military standards (1-4), nationally recognized performance guidelines (5-6), Aeromedical Research Procedure's Guide(9), electrical safety standards (4), and the Propaq User's Guide and Service Manual (10). A test setup and performance check were developed to evaluate the 106EL's performance throughout testing.

BASELINE PERFORMANCE

The baseline performance assessment involved an initial inspection, electrical safety analysis, and following development of a specific test procedure for the device, a baseline performance check.

Initial Inspection

The 106EL was inspected for quality of workmanship, production techniques and potential damage incurred during shipment.

Electrical Safety

Biomedical equipment technicians and aeromedical research engineers performed this evaluation on the 106EL to ensure the safety of both the equipment operator and the patient. This assessment involved measuring the equipment's leakage current and ground to chassis resistance, in addition to a general inspection of the device. The required limits are established in National Fire Protection Agency (NFPA) 99 Health Care Facilites Code (6), and Equipment Management in Hospitals AFI 41-201 (7), Electrical Shock Hazards AFI 41-203 (8).

Test Setup and Performance Check

A test setup and performance check were developed to evaluate the 106EL's operation in accordance with manufacturer/customer specifications throughout the various testing conditions.

a. Test Setup. Plug the 3-lead ECG cable into the ECG port on the 106EL. Attach the 3 ECG leads to the corresponding color coded receptacles on the BIO-TEK Lionheart multiparameter simulator (Lionheart). Plug the YSI temperature cable into the temperature port on the 106EL. Attach the tri-axil end of the temperature probe into the 300 series temperature output of the Lionheart. Configure the Lionheart with the following settings: temperature, 30°C; lead select, I/II; ECG amplitude, 1.0; and ECG BPM, 60. Secure the non-invasive blood pressure (NIBP) tubing line to the NIBP port. Use a T connector to place the Dynatech Nevada Cufflink NIBP Analyzer (Cufflink) cuff connect port in line between the BP cuff and the 106EL. Wrap the BP cuff tightly around the appropriate adult cuff mandrel. For an adult cuff use 2 end and 2 spacer blocks. After zeroing the transducer and allowing the Cufflink to warm up for 15-20 minutes, configure the Cufflink with the following settings: ADAMS Adult, 120/80

(90). Ensure the Cufflink is disconnected from any tubing while zeroing the transducer. Plug the SpO_2 cord into its corresponding port on the SpO_2 port on the 106EL. Attach the free end of the SpO_2 line to the Nellcor pocket tester. Plug the CO_2 sensor cord into its corresponding port on the 106EL's CO_2 module. Attach an airway adapter and sensor to the CO_2 line. Plug the invasive pressure sensor line into its corresponding P1 port on the 106EL. Zero P1 through the sensor options menu and configure the 106EL to monitor ECG lead II and display temperature in °C. The 106EL will continuously monitor temperature, P1, SpO_2 and CO_2. The NIBP operation can be initiated manually or programmed at set intervals. Set the 106EL so that it will not print Apnea tickets, and, when using the printer, limit paper usage by rewinding paper after individual tests.

b. Performance Check. The Performance Check as outlined in the approved test plan was used to validate the function of the 106EL in each of the test conditions. Measurements were taken during initial operation at standard ambient conditions and served as a baseline for later comparison. The performance check consisted of recording the values for each monitored physiologic parameter three times and activating the printer to ensure its function. In many cases the 106EL was continuously monitored through the duration of the test, with the performance checks occurring at defined intervals throughout the test.

ELECTROMAGNETIC COMPATIBILITY

Electromagnetic compatibility testing is a primary concern for equipment to be used on USAF aeromedical evacuation aircraft. This is mainly for the safety of everyone on board the aircraft and the effects of excessive electromagnetic emissions may have on aircraft navigation and communication equipment. Additionally, medical devices may be susceptible to fields generated by the aircraft equipment or other medical devices, and may malfunction in their presence.

The 106EL was evaluated for compliance with MIL-STD-461D (1) - susceptibility field strength levels were less than the D standard requires (refer to RS 103 below). WL/AAWA-2, Wright-Patterson AFB, personnel performed the evaluation in their electromagnetic compatibility facility, with Aeromedical Research personnel present. ASC/ENAI personnel evaluated the electromagnetic compatibility data and determined the airworthiness of the medical device. Specific tests conducted were as follows:

a. Radiated Emissions (RE-102): "Radiated Emissions, Electric Field, 10 kHz to 18 GHz." For Air Force aircraft applications, radiated emissions were tested in a range of frequencies from 2 MHz to 1 GHz. This test determined the amount of EMI emitted by the equipment during its operation. This test was performed to ensure that the device did not affect other pieces of equipment that may be susceptible to electromagnetic emissions (i.e., aircraft navigation and communication equipment).

b. Conducted Emissions (CE-102): "Conducted Emissions, Power Leads, 10 kHz to 10 MHz." For Air Force aircraft applications, conducted emissions were tested throughout the band of 10 kHz to 10 MHz. This test measured emissions generated by the medical device along its power supply lines. This test was performed to ensure that operating the device using line power did not affect other items connected to the same power source, particularly aircraft systems.

c. Radiated Susceptibility (RS-103): "Radiated Susceptibility, Electric Field, 10 kHz to 40 GHz." For Air Force aircraft applications, radiated susceptibility was tested in a frequency range from 30 MHz to 12.4 GHz at the following field strength levels: 20 V/M below 1 GHz and 60 V/M above 1 GHz (field strength values from Table IV, category Aircraft Internal, of 461D). Because the 106EL was a device tested as the laboratory was switching from 461C to 461D, the field strength levels were as depicted in figure 3 below. This test determined whether or not the device would withstand pre-defined levels of EMI generated by antennas both internal and external to the aircraft.

POWER SOURCE	FREQUENCY (MHz)	FIELD STRENGTH (V/M)	461D FIELD STRENGTH (V/M)
115VAC/60Hz	30-990	10	20
	990-1,000	20	20
	1,000-3,000	20	60
	3,000-8,000	60	60
	8,000-12,000	60	60
BATTERY	30-200	20	20
	200-400	10	20
	400-1,000	20	20
	1,000-12,000	60	60
28VDC	30-200	20	20
	200-400	10	20
	400-1,000	20	20
	1,000-12,000	60	60

Fig. 3 Field Strength Levels for Propaq 106EL RS103 Testing.

d. Conducted Susceptibility (CS-101): "Conducted Susceptibility, Power Leads, 30 Hz to 50 kHz." For Air Force aeromedical aircraft applications, conducted susceptibility was tested throughout the entire frequency band, from 30 Hz to 50 kHz. This test determined whether the components "withstood ripple voltages associated with allowable distortion of power source voltage wave forms."(1)

e. Conducted Susceptibility (CS-114): "Conducted Susceptibility, Bulk Cable Injection, 10 kHz to 400 MHz." For Air Force aeromedical aircraft applications conducted susceptibility was tested throughout the frequency band, from 10 kHz to

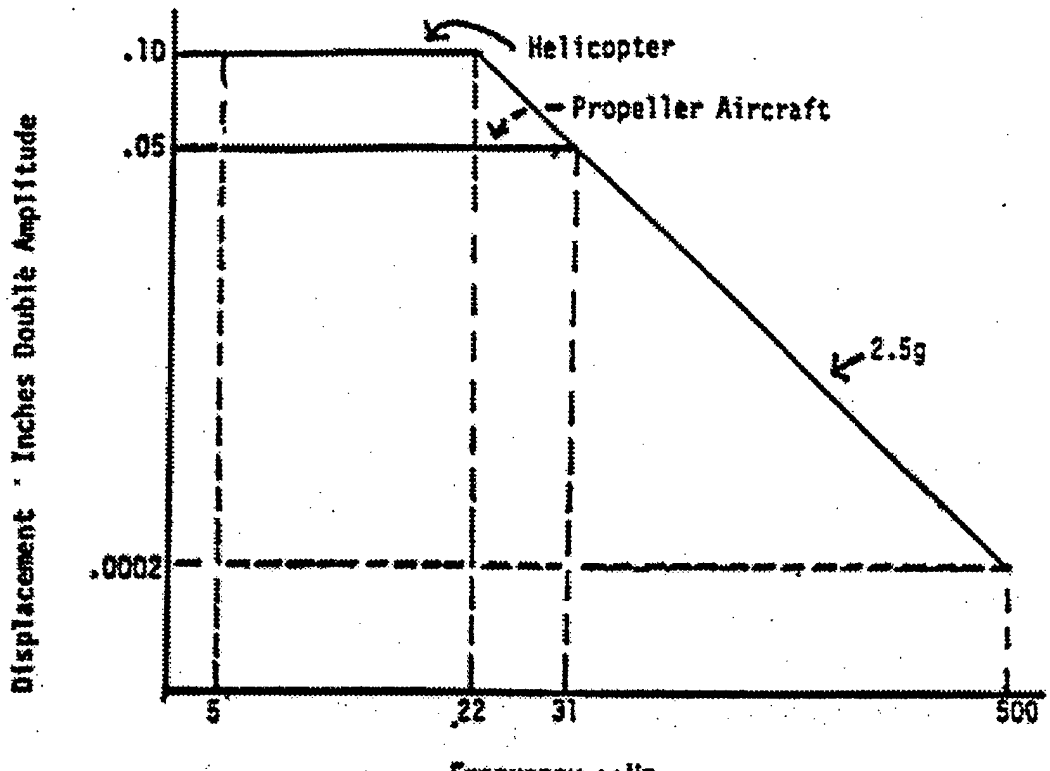
200 MHz. This test was performed to determine whether "simulated currents which were developed on platform cabling from electromagnetic fields generated by antenna transmission affected the equipment under test."(1)

f. Conducted Susceptibility (CS-115): "Conducted Susceptibility, Bulk Cable Injection, Impulse Excitation." This test was performed to ensure the 106EL could withstand the "fast rise and fall time that may be present due to platform switching operations and external transient environments such as lightning and electromagnetic pulse." (1)

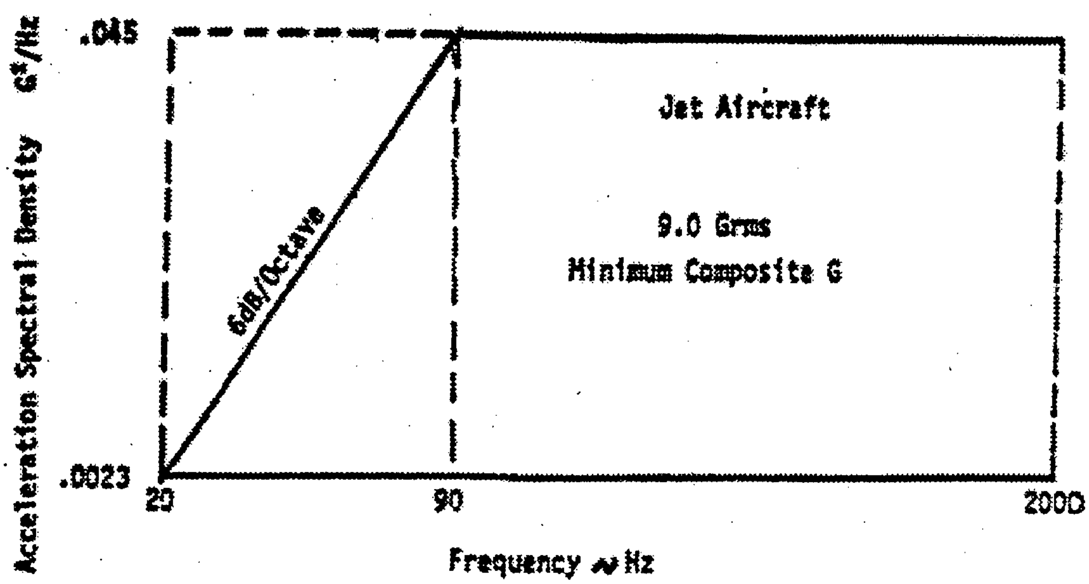
During emissions testing, all options were operated for the duration of the test to create the "worst case" emissions scenario. Throughout the testing, the recorder (printer) ran continuously, and the apnea alarm continuously sounded at maximum volume. The 106EL was in turbo-cuff mode, such that the NIBP option was continuously activated. For susceptibility testing, the unit was operated as discussed earlier in the equipment set-up and performance check sections. For both emissions and susceptibility testing, the 106EL was tested for operation on 115 VAC/60 Hz, 28 VDC, and internal batteries.

VIBRATION

Vibration testing is critical to determine "the resistance of equipment to vibrational stresses expected in its shipment and application environments" (3). Vibration testing was conducted at Aeromedical Research's vibration facility. This testing involved a set of operational tests performed along each of the three axes of the 106EL, X, Y, and Z, with the 106EL mounted on the simulated litter on the shaker head as it would most likely be found in the aircraft. It was subjected to vibration curves with slightly modified levels and lengths from those derived from MIL-STD-810E, Category 10, figures 514.4-16 and 514.4-17 (Fig. 4).



Sinusoidal Vibration Test Curve



Random Vibration Test Curve

Fig. 4 MIL-STD-810E, Category 10, figures 514.4-16 and 514.4-17

ALTITUDE/RAPID DECOMPRESSION

Testing was conducted in the Armstrong Laboratory research chambers which were operated and monitored by chamber operations personnel assigned to the Systems Research Branch (CFTS) of the Crew Technology Division at Armstrong Laboratory, Brooks AFB, TX.

a. Hypobaric Chamber Testing: Altitude testing is critical for aeromedical evacuation equipment due to the potential effects of barometric pressure changes on the equipment. A majority of the aircraft that are characterized as opportune aircraft available for use in aeromedical evacuation pressurize their cabin to barometric pressures equivalent to 8,000-10,000 feet above sea level. However, the differences in pressures can be critical to the effective operation of some medical equipment. Altitude testing consisted of operating the 106EL while ascending from ground level to 10,000 feet (maintaining altitude for one hour) and then descending back to ground, at rates of 5000 ft/min, while stopping at 2000 ft increments to allow for performance checks.

b. Rapid Decompression Testing: Rapid decompression is caused by the loss of aircraft cabin pressurization and subsequent pressure equalization with ambient atmospheric pressures. It is important to determine how medical equipment will function during and after such a decompression and ensure that it will not endanger a patient, the aircraft personnel, or the aircraft itself. The 106EL operated inside the rapid decompression test chamber as the chamber was pressurized to an equivalent of 8,000 ft (2,438 meters) altitude. Then, the pressure in the chamber altitude was taken to the equivalent of 40,000 ft (12,192 meters) over a period of 60 seconds, held at 40,000 ft for a few minutes, and then brought back down to ground level pressure at a rate of 10,000-12,000 ft/min. The test was repeated twice with the decompressions occurring over seven and one seconds, respectively. The 106EL was monitored throughout the series of decompressions, including performance checks each time the unit returned to ground level. The simulator equipment remained outside the chamber. Cables joining the Lionheart, Cufflink, and Nellcor to the 106EL were run through putty-sealed access ports in the chamber walls.

THERMAL/HUMIDITY

Extreme temperature and humidity testing is critical to determine if aeromedical equipment can be stored and operated under severe environmental conditions "without experiencing physical damage or deterioration in performance." Extreme environmental conditions can have numerous detrimental effects on medical equipment including, but not limited to, changes in material characteristics and material dimensions, possible overheating, changes in lubricant viscosity, changes in electronic components, and electronic or mechanical failures due to rapid water or frost formation.

Testing was conducted in the Armstrong Laboratory environmental research chambers which were operated and monitored by chamber operations personnel assigned to the Systems Research Branch (CFTS) of the Crew Technology Division at Armstrong Laboratory, Brooks AFB, TX. The 106EL was placed in the center of the environmental chamber. All input and output cables and wires were routed through a port in the chamber wall, which was subsequently sealed with a precut sponge plug. The other components of the test setup were outside the chamber. For operational tests, the 106EL was monitored continuously, and a performance check was conducted every fifteen minutes. For storage tests, the 106EL was placed in the chamber and remained nonoperational throughout the storage portion of the test. The following describe the conditions of the environmental tests performed:

a. Humidity: 94 +/- 4% Rh, 85°F +/- 3.6°F (29.5°C +/- 2°C) for 4 hrs

b. Hot Temp. Operation: 120°F +/- 3.6°F (49°C +/- 2°C) for 2 hrs

c. Cold Temp. Operation: 32°F +/- 7.2°F (0°C +/- 4°C) for 2 hrs

d. Hot Temp. Storage: 140°F +/- 3.6°F (60°C +/- 2°C) for 6 hrs

e. Cold Temp. Storage: -40°F +/- 3.6°F (-40°C +/- 2°C) for 6 hrs

AIRBORNE FEASIBILITY

Airborne feasibility evaluations are an invaluable means of validating a piece of equipment for clinical and operational suitability under actual operating conditions. By carefully evaluating medical equipment items in their actual environment, Aeromedical Research ensures that all pertinent casualty care issues are adequately addressed by the test protocols. Ensuring safe and effective clinical operation of medical equipment is the primary goal of the inflight evaluation and forms the basis for subsequent recommendations to the users.

This phase of inflight testing was conducted by a Biomedical Research engineer and an aircraft-qualified Aeromedical Research technician on board a C-9 aeromedical evacuation mission. Throughout the flight, the 106EL was secured to either equipment brackets on a NATO litter or Waters bracket secured to a stanchion pole. Human factors characteristics, securing methods, and equipment setup times and locations were also evaluated.

RESULTS

Aeromedical Research evaluated the non-invasive blood pressure (NIBP) option on the 106EL throughout all stages of testing. However, Protocol's NIBP algorithm utilizes a relationship between the blood pressure and the electrocardiogram when determining NIBP, particularly to avoid accepting environmental artifact as pulses. Without this synchronization between our simulators during testing, the NIBP values were within 10% of the simulator, an accuracy recommended by ECRI, as it is comparable to those "obtained by an experienced nurse using a stethoscope and an occluding cuff." However, through several portions of testing, the 106EL was intermittently unable to determine the blood pressure. The 106EL would flash errors such as "measurement time out" or "no valid blood pressure found." Protocol's NIBP algorithm experts and Aeromedical Research engineers have pinpointed these errors as results of the non-synchronized simulators. However, without using synchronized simulators it is impossible to verify the Propaq's ability to consistently take a NIBP.

BASELINE PERFORMANCE

Initial inspection results revealed no manufacturing defects. The 106EL leakage current and ground resistance characteristics remained within allowable limits for battery, 28VDC and 115VAC/60Hz operation.

ELECTROMAGNETIC COMPATIBILITY

The 106EL passed all phases of electromagnetic compatibility testing in both the monitoring and printing mode with one exception. The 106EL temperature option exhibited susceptibility during CS114. ASC/ENAI experts determined that these susceptibility events would be brief (seconds), but that the temperature readings "should not be relied on in critical situations." Aeromedical Research discussed this issue with HQ AMC/SGXR who concluded this situation was not critical, as the crew would have alternate methods of temperature determination. As a result, Aeromedical Research recommends that the user be aware of the potential for temporarily, inaccurate temperature readings. After initial electromagnetic interference evaluations, ASC/ENAI, Wright Patterson AFB, approved the 106EL for use on large-bodied USAF aircraft only. They also recommended that the 106EL be individually evaluated for each small aircraft platform. Aeromedical Research and ASC/ENAI did evaluate and certify the 106EL for use inflight on the C-21. The 106EL will require additional evaluations to fly on other small aircraft. Additionally, ASC/ENAI recommends that "the 106EL not be operated during takeoff and landing when used on smaller air vehicles."

VIBRATION

The 106EL operated within manufacturer's specifications throughout the vibration testing.

ALTITUDE/RAPID DECOMPRESSION

a. Altitude: The 106EL operated within manufacturer's specifications during altitude testing.

b. Rapid Decompression: The 106EL operated within manufacturer's specifications following each rapid decompression and did not present a safety hazard throughout the decompression. However, during rapid decompression testing, the 106EL experienced the following: (1) internal "altimeter failure, rate" which renders the carbon dioxide and breath rate sensors inoperative, and (2), cuff "overpressure condition, cycle power" which renders the cuff inoperative. To recover the carbon dioxide and breath rate sensor, simply disconnect and reconnect the sensor from the 106EL. In a cuff overpressure condition, the unit will continue to operate; however, to recover the cuff channel, simply cycle the power by turning the unit off and then on. Aeromedical Research recommends that personnel be aware of the following potential occurrences during a rapid decompression and be knowledgeable on how to recover the unit.

THERMAL/HUMIDITY

The 106EL experienced problems during both operational and storage temperature evaluations. The carbon dioxide and breath rate sensor ceased operation during the laboratory's hot operation test because it is only designed to operate within a limited ambient temperature range (50°F to 104°F). The sensor recovers when the temperature returns within the acceptable range; however, this is not automatic. The operator must unplug the CO_2 connector and then plug it back in to reactivate the sensor. Aeromedical Research recommends restricting operational use in extreme hot/cold environments if the carbon dioxide and breath rate sensor is a critical portion of patient monitoring. Additionally, Aeromedical Research recommends that the unit only be stored in environmentally controlled areas because of unit failures during cold storage testing and subsequent conversations with Protocol's engineers concerning temperature sensitive components not designed to meet Aeromedical Research's extreme storage temperature specifications.

AIRBORNE FEASIBILITY

The inflight evaluation of the 106EL was successfully completed with the following comments: (1) the audible alarms are difficult to hear in the noisy aircraft environment, and (2), the alarm indications are difficult to view from the side of the unit. For these reasons, Aeromedical Research recommends that the 106EL be mounted such that a crew member is consistently monitoring the display from a front view. The securing capabilities with the 106EL are adequate, utilizing litter equipment brackets with litter straps or the Waters bracket. However, patient connectors and the display limit positioning of the cargo straps and may result in the user needing a more adequate mounting system for the 106EL. Analysis of flight data indicated this unit was easy to enplane and deplane and was compatible with aircraft electrical systems.

CONCLUSIONS

The test and evaluation of Protocol System's Propaq 106EL, SN: AE00127, and expansion modules, SN: BD00128, MD00153 and CI00128, is complete. Aeromedical Research found this unit conditionally acceptable for use during all phases of flight on large-bodied USAF aircraft and inflight on the C-21 only while operating on battery, 115 VAC/60 Hz, and 28 VDC in the aeromedical evacuation environment with the following comments and recommendations:

a. Aeromedical Research recommends that the unit only be stored in environmentally controlled areas because of unit failures during cold storage testing and subsequent conversations with Protocol's engineers concerning temperature sensitive components not designed to meet military extreme storage temperature specifications.

b. Because the carbon dioxide and breath rate sensor is designed to operate within a limited ambient temperature range (50°F to 104°F) and ceased operation during the laboratory's hot operation test (120°F), Aeromedical Research recommends restricting operational use in extreme hot/cold environments if the carbon dioxide and breath rate sensors are a critical portion of patient monitoring. The sensor recovers when the temperature returns within the acceptable range; however, this is not automatic. The operator must unplug the CO2 connector and then plug it back in to reactivate the sensor.

c. Aeromedical Research recommends that personnel be aware of the following potential occurrences during a rapid decompression and be knowledgeable on how to recover the unit. During the laboratory rapid decompression, the 106EL experienced the following: (1) internal "altimeter failure, rate" which renders the carbon dioxide and breath rate sensors inoperative, and (2), cuff "overpressure condition, cycle power" which renders the cuff inoperative. However, neither of these conditions present a safety hazard, and both are correctable when the aircraft returns to cruising altitude or ground. To recover the carbon dioxide and breath rate sensors, simply disconnect and reconnect the sensors from the 106EL. In a cuff overpressure condition, the unit will continue to operate; however, to recover the cuff channel, simply cycle the power by turning the unit off and then on.

d. Aeromedical Research evaluated the non-invasive blood pressure (NIBP) option on the 106EL. Protocol's NIBP algorithm utilizes a relationship between the blood pressure and the electrocardiogram when determining NIBP, particularly to avoid accepting environmental artifact as pulses. Without this synchronization between our simulators during testing, the NIBP values were within 10% of the simulator, an accuracy recommended by ECRI as it is comparable to those "obtained by an experienced nurse using a stethoscope and an occluding cuff." However, through several portions of testing, the 106EL was intermittently unable to determine blood pressure. The 106EL would flash errors such as "measurement time out" or "no valid blood pressure found." Protocol's NIBP algorithm experts and Aeromedical Research engineers have determined these errors were a result of using non-synchronized simulators. However, without using synchronized simulators it is difficult to verify the Propaq's ability to consistently take a NIBP.

e. The 106EL temperature option exhibited susceptibility during electromagnetic interference testing. ASC/ENAI experts determined that these susceptibility events would be brief (seconds), but that the temperature readings "should not be relied on in critical situations." Aeromedical Research discussed this issue with HQ AMC/SGXR who concluded this situation was not critical as the crew would have alternate methods of temperature determination. As a result, Aeromedical Research recommends that the user be aware of the potential for temporarily, inaccurate temperature readings.

f. Aeromedical Research recommends that the 106EL be mounted such that a crew member is consistently monitoring the display from a front view as the audible alarms are difficult to hear in the noisy aircraft environment and the alarm indications are difficult to view from the side of the unit. The securing capabilities with the 106EL are adequate, utilizing litter equipment brackets with litter straps or the Waters bracket. However, patient connectors and the display limit positioning of the cargo straps and may result in the user needing a more adequate mounting system for the 106EL.

g. The 106EL has many additional features/options to include: HP connectors, multiple power adapters, and defibrillator synchronization. The 106EL is certified for use with the UPA/Style B 503-0054-00 Power Adapter and the Abbott Critical Care invasive pressure sensor, the Transpac IV Single Pressure Kit, part # 4285-05. It is not certified for use with defibrillator synchronization, other power adapters, or HP connectors.

h. After initial electromagnetic interference evaluations, ASC/ENAI, Wright Patterson AFB, approved the 106EL for use on large-bodied USAF aircraft only and recommended that the 106EL be individually evaluated for each small aircraft platform. Aeromedical Research and ASC/ENAI did evaluate and certify the 106EL for use inflight on the C-21. The 106EL will require additional evaluations to fly on other small aircraft. ASC/ENAI recommends that "the Propaq not be operated during takeoff and landing when used on smaller air vehicles."

REFERENCES

1. MIL-STD-461D, Electromagnetic Emission and Susceptibility Requirements for the Control of Electromagnetic Interference, Category A1e.

2. MIL-STD-462 D, Measurement of EMI Characteristics.

3. MIL-STD-810 E, Environmental Test Methods and Engineering Guidelines.

4. MIL-STD-1472, Human Engineering Design Criteria for Military Systems, Equipment, and Facilities.

5. Emergency Care Research Institute (ECRI), Physiologic Patient Monitors, Vol 20 Nos. 3-4.

6. National Fire Protection Agency (NFPA) 99, Health Care Facilities Code

7. AFI 41-201, Equipment Management in Hospitals.

8. AFI 41-203, Electrical Shock Hazards.

9. Aeromedical Research Procedures Guide (draft), Internal Operating Instruction, Armstrong Laboratory, Systems Research Branch.

10. PROPAQ 106EL Service Manual and User's Guide.

APPENDIX

SPECIFICATIONS OF THE PROTOCOL SYSTEMS PROPAQ 106EL PHYSIOLOGIC PATIENT MONITOR

ECG SPECIFICATIONS

CONNECTOR	AAMI 6 pin or Hewlett-Packard compatible 12-pin style connector (optional).
SELECTABLE LEADS	I, II, III
LEAD FAULT INDICATOR	LA, LL, RA, MULTIPLE
ECG SIZE IN mV/cm	4, 2, 1, .5, .2
DISPLAY SWEEP SPEEDS	12.5, 25, and 50 mm/sec
QRS TONE VOLUME	High, Low, Medium, Off
QRS TONE FREQUENCY	2625Hz; variable pitch with SpO_2 option and SpO_2 being monitored
FREEZE BUFFER	4.25 secs at 25 mm/sec
BANDWIDTH	.5 to 40 Hz
INPUT PROTECTION	Electrosurgery and defibrillator protected. All models also include electrosurgery interference suppression
LEAD FAIL SENSE CURRENT	25nA dc for active leads 50nA dc for driven leads
TALL T-WAVE REJECTION	Meets and exceeds AAMI (USA) EC-1983, section 3.1.2.1, part 3, for 1.2 mV T-wave and 1mV QRS using AAMI test waveform
COMMON MODE REJECTION	<1mV p-p RTI for 10Vrms, 50/60Hz input, input unbalanced, FILTER function OFF <.1mV p-p RTI for 10Vrms, 50/60Hz input, input unbalanced, FILTER function ON
INPUT IMPEDANCE	>2.5 MΩ differential at 60Hz
INPUT RANGE (ac)	+/- 5mV
INPUT RANGE (dc)	up to +/- 300mV
QRS DETECTOR	Width range: 25-120 ms amplitude Range: .3 to 5mV (RTI)
HEART RATE COUNTER RANGE	25-250 bpm
HEART RATE METER RESPONSE TIME	Responds to change in heart rate within 5-9 seconds depending on physiological waveform. (Including AAMI 3.1.2.1 parts 6 and 7 waveforms.) Includes 1 second readout update interval.
HEART RATE ACCURACY	+/- 3 bpm or 3%, whichever is greater
HEART RATE AVERAGING METHOD	see User's Guide
DRIFT TOLERANCE	80 bpm indicated for 80 bpm ECG plus drift waveform
PACER DISPLAY	Pacer indicator shown on screen if PACER function turned on; pacer spike always shown if of sufficient amplitude.
PACER PULSE REJECTION	see User's Guide
RESPONSES TO IRREGULAR RHYTHM	
Ventricular Bigeminy (VB)	77-82 bpm
Slowing Alternating VB	63-81 bpm
Rapid Alternating VB	115-123 bpm
Bidirectional Systole	87-93 bpm

INVASIVE PRESSURE SPECIFICATIONS

TRANSDUCER TYPE	Strain-gauge resistive bridge
TRANSDUCER EXCITATION IMPEDANCE RANGE	200 - 2000 Ω
TRANSDUCER SENSITIVITY	5 micro V/V/mmHg
EXCITATION VOLTAGE	5 V pulsed dc @ 181 Hz
CONNECTOR	ITT-Cannon plug MS3106F-14S-6P Std. Hewlett-Packard compatible 12 inch connector
BANDWIDTH	digital filtered, dc to 25 Hz
ZERO DRIFT	+/- 1mmHg without transducer drift
ZERO ADJUSTMENT	+/- 200 mmHg including transducer offset
NUMERIC ACCURACY	+/- 2mmHg or 2% of reading, whichever is greater, plus the transducer error
PRESSURE RANGE	-30 to 300 mmHg
PULSE RANGE	25-250 bpm
LEAKAGE CURRENT	Meets ANSI/AAMI risk requirements
ELECTROSURGERY SUPPRESSION	Included in all EL display monitors

CUFF SPECIFICATIONS

METHOD	Oscillometric
CONTROL	Automatic and manual measurement control
AUTO INTERVALS	1, 2, 3, 5, 10, 15, 30, and 60 minutes
TURBOCUFF	Maximum measurements allowable in a 5 minute period
DISPLAYED PRESSURES	Systolic, Diastolic, and Mean plus on-screen monitor
CUFF SIZES:	
Adult	25-35 cm
Large Adult	33-47 cm
Thigh	46-66 cm
Child	18-26 cm
LIMB CIRCUMFERENCE	18-66 cm
HOSE CONNECTION	Quick connect
SYSTOLIC RANGE	30-250 mmHg
DIASTOLIC RANGE	20-230 mmHg
MEAN RANGE	25-240 mmHg
NUMERIC ACCURACY	+/- 3 mmHg or 2%, whichever is greater
MINIMUM INFLATION PRESSURE	100 mmHg
DEFAULT INFLATION PRESSURE	Adult - 140 mmHg, Child - 120 mmHg
CUFF OVERPRESSURE	260 mmHg
CUFF OVERPRESSURE BACKUP	280-330 mmHg
PLUMBING LEAK RATE	< 8 mmHg/min measured at 250 mmHg after 30 seconds for pressure stabilization
PULSE RATE RANGE	25-160 bpm (without ECG) 25-200 bpm (with ECG)
PULSE RATE ACCURACY	6 bpm or 6%, whichever is greater
MAXIMUM DETERMINATION TIME	3 minutes
TYPICAL DETERMINATION TIME	15-40 seconds
TYPICAL DETERMINATION TIME WITH ARTIFACT	up to 70 seconds
MINIMUM TIME BETWEEN MEASUREMENTS	25 seconds
ELECTROSURGERY SUPPRESSION	Included in all EL display monitors

PULSE OXIMETRY

RANGE	0-100%
PROBE ACCURACY (specified at 28-42°C)	70-100% +/- 2 digits, 0-70% unspecified
PULSE RATE RANGE	20-250 bpm
PULSE RATE ACCURACY	+/- 3 bpm
SENSOR COMPATIBILITY	Compatible only with NELLCOR sensors listed in Chapter 2 of the User's Guide
ELECTROSURGERY SUPPRESSION	Included in all units, whether EL or LCD

CO_2 OPTION

CO_2 SENSOR	
Sensor type	Mainstream
Principle of operation	NDIR single-beam, singlepath/wavelength, ratiometric
Warm-up time	20 sec typical, 3 min maximum
Response time	30 mS typical, 60 mS maximum
Calibration	Verify semi-annually, calibrate only as required
CO_2 SENSOR AND CABLE DIMENSIONS AND WEIGHT	
Sensor Height	1.003 in
Sensor Width	1.036 in
Sensor Depth	.78 in
Sensor Weight	< .39 oz
Sensor Volume	.81 cubic inches
Cable Length	10 ft nominal
CO_2 AIRWAY ADAPTER	
Type	Per ISO 3040, single-use
Size	15 mm ID (meets ISO specifications)
Material	clear polycarbonate, with sapphire windows
Deadspace	< 5 cc
CO_2 DISPLAY	
Screen display	CO_2 waveform and $ETCO_2$ and $INCO_2$ numerics
Measurement ranges	$ETCO_2$: 0-99 mmHg, 0-13 kPa, 0-23% $INCO_2$: 0-25 mmHg, 0-5 kPa, 0-5%
Display ranges	$ETCO_2$ and $INCO_2$ same as measurement range
Units	mmHg, kPa, %; user-selectable
Sweep speed	3.13, 6.25, 12.5 mm/sec; user-selectable
Response modes	FAST: 15 sec sampling time period NORMAL: 30 sec sampling time period SLOW: 45 sec sampling period
Gas compensation	see User's Guide
Alarm limit ranges	$ETCO_2$: 0-99 mmHg, 0-14 kPa, 0-14% $INCO_2$: N/A-25 mmHg, N/A-5 kPa
Resolution	1 mmHg
Accuracy	+/- 3 mmHg (0-30 mmHg CO_2) +/- 10% of reading (31-99 mmHg CO_2)
Waveform rise time	130 mS maximum
Altitude error	+/- .4%/1000 ft
BREATH RATE DISPLAY	
Screen display	numeric
Units	bpm
Range	1-99 bpm
Resolution	+/- 1 bpm
Accuracy	+/- 1 bpm or 5%, whichever is greater

APNEA ALARMS AND TICKETS	
Apnea ticket	set to auto print after apnea event and after 1 minute continued apnea
Apnea alarm accuracy	+/- 1 sec
Resolution	5 sec
Alarm limits range, adult and pediatric	15-30 sec delay, 5 sec increments
BAROMETRIC PRESSURE	
Pressure compensation	automatic
Operating range	-2000 ft to15,000 ft
Screen display	numeric (CO_2 status window)
Units	mmHg
Accuracy	+/- 2.5% of reading (calibrated at sea level)
IN-SERVICE VALUES	
$ETCO_2$	initial value: 38, alternate value: 60
$INCO_2$	initial value: 0, alternate value: 8
Breath rate	initial value: 12, alternate value: 31
CO_2 SENSOR ENVIRONMENTAL SPECIFICATIONS	
Sensor housing temperature	42°C nominal
Operating ambient temperature	10° to 40°C
Storage temperature	0-50°C
Operating altitude	-2000 ft to 15000 ft
Storage altitude	30000 ft
Storage humidity	0 to 95%, noncondensing
Shock	100 g for 4 msec
Vibration	5-35 Hz, .015 in p-p 35-100 Hz, 1 g acceleration
Drop	36 inches free fall to floor (tile over concrete, one drop each face, one drop each edge/corner)

TEMPERATURE

RANGE	17°C to 50°C; 62.6°F to 122°F
DISPLAYS	T1
PROBES	Compatible with YSI Series 400 and 700 and Electromedics Series 2100 probes. HP side panel only compatible with YSI 400 and has HP connector
UNITS	°C or °F, user selectable
ACCURACY	+/- .1°C (+/- .2°F) plus probe tolerance
RESOLUTION	.1°C or °F
ELECTROSURGERY SUPPRESSION	Included in all EL display monitors

ALARMS

INDICATORS	ALARM light, ALARM(S) OFF light, Audible tone Lights continually flash .5 secs on and .5 secs off if an alarm is suspected Flashing Numerics. Numeric in violation alternates between normal and reverse video with 1 second duration each.
TONE FREQUENCY	2625 Hz Tone is steady for a patient alarm and sounds for 1 second every 4 seconds for an equipment alert
SELECTABLE TONE VOLUME	low, medium, high
LIMITS	settable on all parameters
CONTROL	Automatic preset or manual settings
ALARM ON TACHYCARDIAS	Most tachycardias will alarm in less than 8

	seconds. These include AAMI 3.1.2.1 part 7 waveforms. Certain multifocal tachycardias may initially alarm as "low rate."
APNEA ALARM LIMITS RANGE, ADULT AND PEDIATRIC	15-30 secs delay, 5 sec increments

TRENDS

MODEL 106 PARAMETERS	CUFF, P1, P2, T1, HR (hear rate/pulse rate), SpO_2, End-tidal CO_2, Inspired CO_2, Breath Rate
DURATION	5 hours displayed, 8 hours printed
RESOLUTION	2 minutes
TYPES	graphic and tabular
SCALES	selectable depending on parameter

DISPLAY

GENERAL	
Matrix	276X128 pixels
Active viewing area	146.2 mmX67.8 mm
Pixel pitch	.53 mmX.53 mm
Character pitch	Large: 8.2 mm (.3in) Small: 3.8 mm (.15in)
ELECTROLUMINESCENT DISPLAY	
Viewing angle	> 160° Horizontal and vertical
Contrast ratio	> 100:1 with contrast enhancement filter
Display window	contrast enhancement filter
Display color	amber
Display background color	black

MONITOR (Environmental)

OPERATING TEMPERATURE	0° to 50°C
SHIPPING AND STORAGE TEMPERATURE	-20° to 60°C
OPERATING ALTITUDE	-2000 to 15000 ft
SHIPPING AND STORAGE ALTITUDE	-2000 to 40000 ft
OPERATING RELATIVE HUMIDITY	0-97%, noncondensing
SHIPPING AND STORAGE RELATIVE HUMIDITY	0-97%, noncondensing
SHOCK	50 g
VIBRATION	Random vibration, .02 g^2/Hz from 10 to 300 Hz, ramping down to .002 g^2/Hz at 500 Hz. Operating 1 hour per axis, 3 hours per test.
ELECTROMAGNETIC INTERFERENCE	per FDA Standard MDS-201-0004 (emissions only)
WATER RESISTANCE	IPX1 Drip-proof per IEC Publication 529

MONITOR (Physical)

PROTECTION CLASSIFICATIONS	
Type of protection against electric shock	
- monitor powered by power adapter	- Class I (protectively earthed)
- monitor powered by internal batteries	- Internally powered equipment
- monitor powered by external low-voltage DC source	- Class II Equipment
Degree of protection against electric shock	- Type CF equipment, Defibrillator-proof

Degree of protection against harmful ingress of water	- IPX1, protected against vertically dripping water
Method of disinfection	- not suitable for autoclaving
Flammable anesthetics	- not suitable for use with flammable anesthetics
MONITOR ONLY	
Height	6.6 in
Width	8.3 in
Depth	4.8 in
Weight	5.8 lb
MONITOR WITH EXPANSION MODULE	
Height	9.8 in
Width	8.3 in
Depth	7.3 in
Weight	10.4 lb

PRINTER

OPERATION	
Operating modes	Continuous, Snapshot, Freeze Print, Auto Interval Print, Auto Interval Trend, Tabular Trend, Alarm Print, Cuff Ticket, Apnea Ticket
Auto Print Intervals	15 min, 30 min, 1 hour, 2 hours, 4 hours
Auto trend shifts	once every 8 hours
Number of waveforms	up to three: ECG, SpO_2, P1, P2, CO_2
Grid	5 mm and 1mm gradations
Annotation	Date, Time, Print mode, Speed, Heart rate, Systolic, Diastolic, Mean, SpO2, Breath rate, ETCO2, INCO2, Temperature, Pacer status
Printing Speeds	6.25, 12.5, 25.0 mm/sec, simulated 6.25
PRINTER MECHANISM	
Printing method	thermally sensitive dot method
Dot structure	320 dots per line
Printing width	53 mm
Horizontal dot pitch	.165 mm, 6 dots/mm
Vertical dot pitch	.165 mm
Paper feed method	friction feed
Paper feed precision	+/- 2% @ 25°C and 60% relative humidity
Paper width	60 mm
Reliability	30 million pulses/dot
ENVIRONMENTAL	
Operating temperature	5° to 40°C
Shipping and storage temperature	-20° to 60°C
Operating relative humidity	35% to 85% noncondensing
Shipping, storage relative humidity	5% to 90% noncondensing
Shipping and operating altitude	-2000 to 15000 ft
Storage altitude	-2000 to 40000 ft
Shock	30 g
Vibration	Random vibration, .02 g^2/Hz from 10 to 300 Hz, ramping down to .002 g^2/Hz at 500 Hz. Operating 1 hour per axis, 3 hours per test.
EMI	per standard MDS-201-0004 (emissions only)
PAPER	
Short-term storage environment (up to 7 days)	-20 ° to 40°C, 5% to 80% RH noncondensing
Long-term storage environment (up to 5 years)	25°C (optimal), 65% RH noncondensing

POWER

MODE OF OPERATION	Continuous
BATTERY PACK TYPE	Sealed lead acid
BATTERY PACK CAPACITY	Monitor only - 8 volts, 3 amp-hours Monitor with expansion modules - 8 volts, 6 amp-hours
BATTERY RECHARGER CIRCUITRY	Internal, powered by external power adapter
DC INPUT POWER REQUIRED	12-28 Volts, 10.5 Watts, w/CO_2: 25 Watts
INPUT FUSE RATING	3 A/250 V, Slow-blow, Type 2 AG (.57X.177 in)
OPERATING TIMES ON BATTERY	Range of 4 to 8 hours depending on product configuration
BATTERY RECHARGE TIME WITH 106EL ON	Range of 8 to 12 hours typical, depending on product configuration
BATTERY RECHARGE TIME WITH 106EL OFF	Range of 6 to 8 hours depending on product configuration

POWER ADAPTERS

UNIVERSAL POWER ADAPTER, PART NO. 503-0054-00

Length	5.0 in
Width	3.6 in
Height	3.1 in
Weight	3.1 lb
Rated input	100-120VAC, 500 mA, 50/60 Hz
Rated fuses	T800 mA/250V, Time-delay, 5X20 mm
Rated output (continuous)	16-24 VDC, 25 watts
Connector	Style B
Additional Features	Detachable power cord, pilot light, mains switch